REMARKS

This Reply is filed in response to the Office Action dated September 15, 2005. Claims 67-134 are pending. Claims 111-134 are hereby cancelled. Claims 74, 82-95, and 97-110 are withdrawn. Claims 67-73, 75-81, and 96 have been rejected. Herein, claims 67, 70, 71, 77-80, 82-86, 88-90, 92, and 94-110 are amended. Claim 67 was amended without narrowing to clarify that the claimed method is directed to different types of transcription factors, and was amended without narrowing to clarify the claimed testing and determination process. Claim 73 is canceled, as discussed, below.

Group 37 is now undergoing prosecution, with Group 37 being claims 67-73, 75-81, and 96 e.g., as provided at page 4 of the Office Action dated March 1, 2005. The species Hey/HRT is being examined (claim 96) and, in the most recent Office Action, three of the four species of claim 75 are being examined: lung cancer, small cell lung cancer, and non small cell lung cancer. Upon allowance of generic claim 67, its dependent claims are to be rejoined and examined.

Our records do not show acknowledgement of the supplemental IDS submitted October 18, 2005. Accordingly, we request that you send an initialed copy of the form acknowledging consideration of the references therein.

Rejection of claim 73 for failing to further limit its parent claim

The Office Action, at ¶8, indicates that the limitation "wherein the cancer is presence of a cancer cell in the host" is redundant relative to its parent claim 67, which claims a cancer. The Office Action points to claim 75 but it is understood that claim 73 was intended. Claim 73 is cancelled without prejudice to expedite prosecution. The

cancellation of this claim is not an admission as to what the ordinary artisan would understand the term "cancer" to mean or how that meaning relates to "a cancer cell in the host". Accordingly, it is believed that dependent claim 73 is not necessarily redundant. Withdrawal of this rejection is requested.

Rejection under 35 U.S.C. §112 ¶1.

Claims 67-73, 75-81, and 96 all stand rejected for lack of enablement. The Office Action maintains that claim 67 is to be examined in light of the elected species Hey/HRT, so that claim 67 is to be examined specifically in light of Hey/HRT. Further, the Office Action takes the position that what is claimed is detection of all the members of Hey/HRT as an indication that the host has NSCLC. The Office Action reported that the Application has no teaching that detection of all the members of Hey/HRT indicates NSCLC. Therefore it concluded that the claim was not enabled.

This Office Action, however, misstates what is claimed. The present amendment clarifies that what is claimed is testing for an autoimmune response against a plurality of transcription factors (e.g., including a Hey/HRT) to thereby determine from a result of the testing that the host has a cancer and to thereby further determine a type of the cancer.

The Application, e.g., at Table 11, enables this claim by showing that NSCLC could be determined by testing for all the factors shown in Table 11, including a Hey/HRT factor. Indeed, HeyL/HRT3 is a good indicator, by itself, for NSCLC but it is not dispositive. Instead, the claimed technique does not rely only just one marker or one particular marker - this characteristic is one of its advantages.

Further, the Office Action has incorrectly taken the position that claim 67 is not enabled if the claim can be construed to read on one embodiment that is not enabled.

Specifically, it argues that there is no teaching that a diagnosis of NSCLC can be based upon detecting exactly three Hey/HRTs transcription factors. The Office Action concludes that there is no enablement of the claim because one embodiment is not enabled.

But this conclusion is clear error. The Federal Circuit has explicitly stated that "Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid [for lack of enablement]." Atlas Powder v. E.I. DuPont (Fed. Cir. 1984) 224 U.S.P.Q. 409, 414. It is simply incorrect to argue that one inoperable embodiment makes a claim non-enabled.

The Office Action seems to take the position that, under the Patent Offices rules for practicing a species restriction, that the claim must be evaluated for enablement based exclusively on one embodiment having the one species under examination. This interpretation of restriction practice, however, is contrary to patent law, as explained above. Patent Office procedural rules are not an adequate legal basis to override federal law because federal law takes precedence over administrative procedures. Further, it is respectfully submitted that the Office Action's application of restriction practice is not supported by Patent Office practice, the MPEP, or the U.S. Code of Federal Regulations.

It is respectfully submitted, therefore, that the Office Action did not show good reasons why the claims are not enabled. Indeed, "When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for

doubting any assertions in the specification as to the scope of enablement." In re Wright 27 USPQ2d 1510, 1513 (Fed Cir 1993).

Rejection of Claims 67-73, 76-81 Under 35 U.S.C. § 102(b) in Light of Mudenda et al. and in Light of Winter et al

Claims 67-73, 76-81 were rejected under 35 U.S.C. § 102(b) in light of Mudenda et al., Br. J. Cancer, 1994, 69:1115-1119. And claims 67, 73, and 75 were rejected under 35 U.S.C. § 102(b) in light of Winter et al., Cancer research, 1992, 52:4168-4174. The Office Action argued that the unamended claims read on detection of at least two p53 proteins and suggested a particular definition for the term "array". It is respectfully submitted that the definition proffered in the Office Action for "array" is not necessarily the meaning that an ordinary artisan would assign to that term; however, this point is moot in light of the amendments to the claims.

Claim 67 was amended to provide that "each of the plurality of transcription factor types are chemically distinct from each other". Accordingly, Mudenda et al. does not anticipate the claimed invention because Mudenda et al. is directed only to p53 and not to a plurality of types of transcription factors that are chemically distinct from each other. Similarly, Winter et al. is directed only to p53 and not to a plurality of types of transcription factors that are chemically distinct from each other.

Further, neither Mudenda et al. nor Winter et al. determined from a result of the testing that the host had a cancer and thereby further determined a type of the cancer. Instead, Mudenda et al. screened breast cancer patients for the presence of p53 autoantibodies and ultimately concluded that their observations "suggest that serological analysis provides an assessment of the functional state of the p53 gene in breast cancer

patients, and may prove to be a useful adjunct to molecular and histochemical methods of tumour characterization" (Mudenda et al., sentence bridging pages 1118-1119). As stated in the Abstract, p53 detection provided "additional information to immunochemistry" and may identify patients with breast cancers that are "aggressive histological types", Mudenda et al. Abstract, last sentence. Mudenda et al. thus did not use their reported methods as claimed, e.g, to determine that the host had a cancer and thereby further determine a type of the cancer.

Similarly, Winter et al. tested cancer patients for p53, finding that p53 antibodies were present in some small cell lung cancer patients and some non-small cell lung cancer patients (Abstract, Winter et al.). Winter et al. explicitly make the point that the "clinical implications of this remain obscure" (Winter et al. page 4173, last paragraph of first column). Indeed, Winter et al. describe the development of anti-p53 antibodies as an interesting model system for studying immune responses in cancer patients against mutant oncogene products (last sentence of Abstract, Winter et al.). Winter et al. thus did not use their reported methods as claimed, e.g, to determine that the host had a cancer and thereby further determine a type of the cancer.

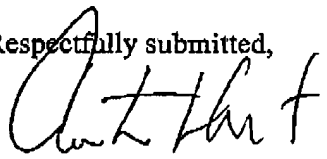
Since neither Mudenda et al. not Winter et al. describe using more than one type of transcription factor and since neither describe using such a factor for diagnosing a cancer and since neither describe using such a factor to determine a type of cancer, it is submitted that neither of these references supply all of the claimed elements. Accordingly, withdrawal of this rejection is requested.

CONCLUSION

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution

Respectfully submitted,



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